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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/856,927	09/19/2001	Michael Dean	015280-382100US	6490
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7590 07/21/2004

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/856,927

Applicant(s)

DEAN ET AL.

Examiner

Sheela J Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/2/04 has been entered.

The rejection under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 remains rejected under 35 U.S.C. 102(a) as being anticipated by Doyle, Proceeding of the American Association for Cancer Research 39:657 (3/98) (reference AE on IDS filed 7/15/03 as evidence by Doyle et al PNAS USA 95:15665 (12/98) (reference AJ on IDS filed 7/15/03). In view of applicant's amendment, the rejection re-written.

This abstract discloses a Breast Cancer Resistance Protein, which is a novel ATP-binding cassette (ABC) transporter. The protein is approximately 663 amino acids in length and as evidenced by the PNAS paper and the sequence alignments attached to the action mailed 8/21/03. The sequence in the PNAS paper and that of the instant invention has 99.8% identity (SEQ ID No. 2). It is the Examiner's position that the protein in the 1996 abstract and that in the PNAS paper are the same, especially in view of the fact that the abstract in the PNAS paper is the same as that of the 1996 abstract.

It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer mitoxantrone resistance to S1-M1-80 human colon carcinoma cells.

Claims 1 and 2 remain rejected under 35 U.S.C. 102(a) as being anticipated by Doyle, Proceeding of the American Association for Cancer Research 39:657 (3/98) (reference AE on IDS filed 7/15/03 as evidence by Doyle et al PNAS USA 95:15665 (12/98) (reference AJ on IDS filed 7/15/03). In view of applicant's amendment, the rejection re-written.

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This abstract discloses a Breast Cancer Resistance Protein, which is a novel ATP-binding cassette (ABC) transporter. The protein is approximately 663 amino acids in length and as evidenced by the PNAS paper and the sequence alignments attached to the action mailed 8/21/03, the sequences in the PNAS paper and those of the instant invention has 99.8% identity (SEQ ID No. 2). It is the Examiner's position that the protein in the 1996 abstract and that in the PNAS paper are the same, especially in view of the fact that the abstract in the PNAS paper is the same as that of the 1996 abstract.

It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer mitoxantrone resistance to S1-M1-80 human colon carcinoma cells.

Claim 1 remains rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al US 6313277 (which has priority to 60/073763, filed 2/5/98). In view of applicant's amendment, the rejection re-written.

This reference discloses a Breast Cancer Resistance Protein (SEQ ID No. 1), which is a novel ATP-binding cassette (ABC) transporter. As evidence by the sequence alignments (see attached), SEQ ID NO. 1 of the reference has 99.4% identity to SEQ ID No. 2.

It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer

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mitoxantrone resistance to S1-M1-80 human colon carcinoma cells. The protein in the reference will bind to polyclonal antibodies that bind SEQ ID No. 2 because the protein in the paper is 99% identical to said sequences.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al US 6313277 (which has priority to 60/073763, filed 2/5/98). ). In view of applicant's amendment, the rejection re-written.

This reference discloses a Breast Cancer Resistance Protein (SEQ ID No. 1), which is a novel ATP-binding cassette (ABC) transporter. As evidence by the sequence alignments (see attached), SEQ ID NO. 1 of the reference has 99.4% identity to SEQ ID No. 2.

It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer mitoxantrone resistance to S1-M1-80 human colon carcinoma cells.

#### Response to Applicant's arguments

Applicant argues that the examiner's position is inconsistent with the standards set forth in the MPEP and cites a portion of 715.02. A complete reading of 715.02 and into 715.03 states the standard for generic claims. In 715.03 the MPEP starts by saying

"Where generic claims have been rejected on a reference ... which discloses a species not antedated by the affidavit or declaration, the rejection will not ordinarily be withdrawn, subject to the rules

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set forth below, unless the applicant is able to establish that he or she was in possession of the generic invention prior to the effective date of the reference”.

In the instant case, applicant has not established the he or she was in possession of the generic invention prior to the effective date of the reference.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

Claims 1-2 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

There is no support for the terminology “being encoded by a nucleic acid capable of under stringent hybridization conditions specifically hybridizing to a polynucleotide sequence, the antisense sequence of the polynucleotide sequence encoding the amino acid sequence of SEQ ID NO:2”. This terminology is not found in the specification as originally filed.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.


It appears that the antisense sequence and the nucleic acid sequence in claim 1 are the same. In view of this, claims 22 and 23 are duplicates.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sheela J Huff  
Primary Examiner  
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